

Message

From: Chun, Melissa [Chun.Melissa@epa.gov]
Sent: 12/18/2018 7:14:37 PM
To: McNally, Robert [McNally.Robert@epa.gov]; Jones, Russell [Jones.Russell@epa.gov]; Varco, Joseph [varco.joseph@epa.gov]; Ambrosino, Helene [Ambrosino.Helene@epa.gov]; Gsell, Alyssa [Gsell.Alyssa@epa.gov]; VanAkkeren, Brett [VanAkkeren.Brett@epa.gov]; Wyatt, TJ [Wyatt.Tj@epa.gov]; Hofmann, Angela [Hofmann.Angela@epa.gov]; Chumble, Prasad [Chumble.Prasad@epa.gov]; Smoot, Cameo [Smoot.Cameo@epa.gov]; Watkins, Stephen [watkins.stephen@epa.gov]; Hoyt, Sarita [Hoyt.Sarita@epa.gov]; Mosby, Jackie [Mosby.Jackie@epa.gov]; Miller, Wynne [Miller.Wynne@epa.gov]
Subject: RE: FROM OMB: EO 12866 Interagency Review: EPA's Guidance for Plant Biostimulant Products: Label Claims Excluded or Regulated under FIFRA as Plant Regulator Claims (RIN 2070-ZA21) - Interagency Comments

Thanks Bob.

From: McNally, Robert
Sent: Tuesday, December 18, 2018 12:14 PM
To: Chun, Melissa <Chun.Melissa@epa.gov>; Jones, Russell <Jones.Russell@epa.gov>; Varco, Joseph <varco.joseph@epa.gov>; Ambrosino, Helene <Ambrosino.Helene@epa.gov>; Gsell, Alyssa <Gsell.Alyssa@epa.gov>; VanAkkeren, Brett <VanAkkeren.Brett@epa.gov>; Wyatt, TJ <Wyatt.Tj@epa.gov>; Hofmann, Angela <Hofmann.Angela@epa.gov>; Chumble, Prasad <Chumble.Prasad@epa.gov>; Smoot, Cameo <Smoot.Cameo@epa.gov>; Watkins, Stephen <watkins.stephen@epa.gov>; Hoyt, Sarita <Hoyt.Sarita@epa.gov>; Mosby, Jackie <Mosby.Jackie@epa.gov>; Miller, Wynne <Miller.Wynne@epa.gov>
Subject: RE: FROM OMB: EO 12866 Interagency Review: EPA's Guidance for Plant Biostimulant Products: Label Claims Excluded or Regulated under FIFRA as Plant Regulator Claims (RIN 2070-ZA21) - Interagency Comments

I can do Jan. 7-8

From: Chun, Melissa
Sent: Tuesday, December 18, 2018 11:55 AM
To: Jones, Russell <Jones.Russell@epa.gov>; McNally, Robert <McNally.Robert@epa.gov>; Varco, Joseph <varco.joseph@epa.gov>; Ambrosino, Helene <Ambrosino.Helene@epa.gov>; Gsell, Alyssa <Gsell.Alyssa@epa.gov>; VanAkkeren, Brett <VanAkkeren.Brett@epa.gov>; Wyatt, TJ <Wyatt.Tj@epa.gov>; Hofmann, Angela <Hofmann.Angela@epa.gov>; Chumble, Prasad <Chumble.Prasad@epa.gov>; Smoot, Cameo <Smoot.Cameo@epa.gov>; Watkins, Stephen <watkins.stephen@epa.gov>; Hoyt, Sarita <Hoyt.Sarita@epa.gov>; Mosby, Jackie <Mosby.Jackie@epa.gov>; Miller, Wynne <Miller.Wynne@epa.gov>
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Hi all,

I talked with Danielle about the biostimulants guidance during our bi-weekly meeting this morning.

She mentioned that USDA had comments on the guidance document that they will send to her today. Danielle will get them to us as soon as she can.

Ex. 5 Deliberative Process (DP)

On page 6, line 115, I added the language that was brought up during staff meeting, i.e., Should we take public comment on whether EPA should consider developing a definition?

Ex. 5 Deliberative Process (DP)

Please note that the call with DOJ will need to be scheduled the 1st week of January. DOJ indicated that they are available on January 3rd, 7th and 8th. Please let me know your availability (2 or more times if possible).

I'm attaching a revised version of the FR Notice.

Thanks!

-Melissa

From: Gsell, Alyssa

Sent: Monday, December 17, 2018 4:04 PM

To: Chun, Melissa <Chun.Melissa@epa.gov>; Jones, Russell <Jones.Russell@epa.gov>; McNally, Robert <McNally.Robert@epa.gov>; Varco, Joseph <varco.joseph@epa.gov>; Ambrosino, Helene <Ambrosino.Helene@epa.gov>; VanAkkeren, Brett <VanAkkeren.Brett@epa.gov>; Wyatt, TJ <Wyatt.Tj@epa.gov>; Hofmann, Angela <Hofmann.Angela@epa.gov>; Chumble, Prasad <Chumble.Prasad@epa.gov>; Smoot, Cameo <Smoot.Cameo@epa.gov>; Watkins, Stephen <watkins.stephen@epa.gov>; Hoyt, Sarita <Hoyt.Sarita@epa.gov>; Mosby, Jackie <Mosby.Jackie@epa.gov>

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For the edits on lines 15-18, could we use "generally are" instead of "may be"? OGC understands that the examples are real life examples, where the claims have been determined to be (or not be) considered PBS. The term "generally are" may be an acceptable compromise between the original EPA language and the proposed OMB language.

Thanks.

Alyssa M. Gsell

US EPA Office of General Counsel

Phone: 202-564-7413

Fax: 202-564-5416

From: Chun, Melissa

Sent: Sunday, December 16, 2018 6:49 PM

To: Jones, Russell <Jones.Russell@epa.gov>; McNally, Robert <McNally.Robert@epa.gov>; Varco, Joseph <varco.joseph@epa.gov>; Ambrosino, Helene <Ambrosino.Helene@epa.gov>; Gsell, Alyssa <Gsell.Alyssa@epa.gov>; VanAkkeren, Brett <VanAkkeren.Brett@epa.gov>; Wyatt, TJ <Wyatt.Tj@epa.gov>; Hofmann, Angela <Hofmann.Angela@epa.gov>; Chumble, Prasad <Chumble.Prasad@epa.gov>; Smoot, Cameo <Smoot.Cameo@epa.gov>; Watkins, Stephen <watkins.stephen@epa.gov>; Hoyt, Sarita <Hoyt.Sarita@epa.gov>; Mosby, Jackie <Mosby.Jackie@epa.gov>

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Hi all,

Here's the mark-up for the FR Notice.

On page 1, lines 15-18, the language "may be" seems appropriate since we are using this guidance to help determine whether product label claims are plant regulator claims or not. Do we need to be more specific?

On page 4, lines 79-84, the revisions to streamline and clarify this section are o.k. I added a sentence from the guidance document that OMB provided on the uncertainty of costs and cost savings. Do we need more detail?

Please forward your comments to everyone on this e-mail.

Thanks!

-Melissa

From: Chun, Melissa

Sent: Friday, December 14, 2018 12:08 PM

To: Jones, Russell <Jones.Russell@epa.gov>; McNally, Robert <McNally.Robert@epa.gov>; Varco, Joseph <varco.joseph@epa.gov>; Ambrosino, Helene <Ambrosino.Helene@epa.gov>; Gsell, Alyssa <Gsell.Alyssa@epa.gov>; VanAkkeren, Brett <VanAkkeren.Brett@epa.gov>; Hofmann, Angela <Hofmann.Angela@epa.gov>; Chumble, Prasad <Chumble.Prasad@epa.gov>; Smoot, Cameo <Smoot.Cameo@epa.gov>; Watkins, Stephen <watkins.stephen@epa.gov>; Hoyt, Sarita <Hoyt.Sarita@epa.gov>; Mosby, Jackie <Mosby.Jackie@epa.gov>

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We walked through the comments, made assignments, and flagged one that will need to be raised to the DAA's.

Russell and Bob are responding to the comments on the guidance document and I'll work on the FR Notice with help from Alyssa on the "are" vs. "maybe" in the summary and TJ on the uncertainty of costs and cost savings.

We'll send the mark-ups around on Monday for folks to comment on.

This is the comment that was flagged in the Summary for the guidance document:

Ex. 5 Deliberative Process (DP)

OMB commented: Recommend soliciting comment on the different proposed definitions and if EPA should consider codifying a definition for PBS in a future rulemaking.

After we've agreed on the responses/edits, the documents will go to Rick and the DAA's on Tuesday for their approval, before sending the responses to OMB.

Please note that there might be a second set of comments from USDA next Tuesday.

Thanks everyone!

-Melissa

Melissa L Chun | US EPA | Regulatory and Information Coordination Staff | Office of Chemical Safety and Pollution Prevention | 1200 Pennsylvania Ave., NW | William Jefferson Clinton Building East Room 3425E, Mail Code 7101M | Washington DC 20460 | phone: (202) 564-1605

From: Chun, Melissa

Sent: Friday, December 14, 2018 9:35 AM

To: Jones, Russell <Jones.Russell@epa.gov>; McNally, Robert <McNally.Robert@epa.gov>; Varco, Joseph <varco.joseph@epa.gov>; Ambrosino, Helene <Ambrosino.Helene@epa.gov>; Gsell, Alyssa <Gsell.Alyssa@epa.gov>; VanAkkeren, Brett <VanAkkeren.Brett@epa.gov>; Hofmann, Angela <Hofmann.Angela@epa.gov>; Chumble, Prasad <Chumble.Prasad@epa.gov>; Smoot, Cameo <Smoot.Cameo@epa.gov>; Watkins, Stephen <watkins.stephen@epa.gov>; Hoyt, Sarita <Hoyt.Sarita@epa.gov>

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Hi all,

Here are the interagency reviewer comments from OMB.

We go through them at 11 am.

-Melissa

Melissa L Chun | US EPA | Regulatory and Information Coordination Staff | Office of Chemical Safety and Pollution Prevention | 1200 Pennsylvania Ave., NW | William Jefferson Clinton Building East Room 3425E, Mail Code 7101M | Washington DC 20460 | phone: (202) 564-1605

From: Jones, Danielle Y. EOP/OMB <Danielle_Y_Jones@omb.eop.gov>

Sent: Friday, December 14, 2018 9:29 AM

To: Chun, Melissa <Chun.Melissa@epa.gov>

Cc: Hofmann, Angela <Hofmann.Angela@epa.gov>; VanAkkeren, Brett <VanAkkeren.Brett@epa.gov>

Subject: EO 12866 Interagency Review: EPA's Guidance for Plant Biostimulant Products: Label Claims Excluded or Regulated under FIFRA as Plant Regulator Claims (RIN 2070-ZA21)

Good morning Melissa,

Please find attached the interagency reviewers comments on the Guidance for Plant Biostimulant Products: Label Claims Excluded or Regulated under FIFRA as Plant Regulator Claims (RIN 2070-ZA21).

Please let me know if you have any questions.

Best,
Danielle

Danielle Y. Jones
Senior Policy Analyst
Office of Management and Budget
Phone: (202) 395-1741 | djones@omb.eop.gov